REDACTED VERSION

DISTRICT OF MASSACHUSETTS

UNITED STATES DISTRICT COURT

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION NO. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: ALL ACTIONS	

AFFIDAVIT OF THOMAS M. SOBOL IN RELATION TO PLAINTIFFS' MOTION TO TAKE ADDITIONAL LIMITED DISCOVERY

I, Thomas M. Sobol, depose and say as follows:

1. I am member of the bar of the Supreme Judicial Court of the Commonwealth of Massachusetts and a member of the United States District Court for the District of Massachusetts. I am a partner at the law firm of Hagens Berman LLP. I am Liaison Counsel and Co-Lead Counsel for the Plaintiffs in the above-captioned action. I submit this affidavit in relation to Plaintiffs' Motion to Take Additional Limited Discovery.

2. In the fall of 2001, civil litigation relating to average wholesale price manipulation commenced in the wake of a series of governmental reports regarding unlawful manipulation of average wholesale prices.

3. While many of these governmental reports focused on abuse within the Medicare system (and its consequent inflation of the 20% co-pay incurred by private payors), the reports also described abuse outside the realm of physician-administered (e.g., injectable) drugs. Those reports chronicled AWP manipulation with respect to a

wide range of oral and injectible drugs, with particular focus on multi-source drugs (i.e., generic drugs, or brand name drugs for which a generic alternative exists).

4. On April 30, 2002, the Judicial Panel on Multidistrict Litigation ruled that "all actions. . . involve common questions of fact concerning (either singly or as part of a conspiracy) the pharmaceutical Defendants engaged in fraudulent marketing sales and/or billing schemes by unlawfully inflating the [AWP] of their Medicare covered prescription drugs in order to increase the sales of these drugs to healthcare professionals and thereby boost the pharmaceutical companies' profits." Order at 3, *In Re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456. (Apr. 30, 2002). As a result, the JPMDL issued an order stating that "actions pending outside the District of Massachusetts and listed on the attached Schedule D are transferred to the District of Massachusetts, assigned to the Honorable Patti B. Saris for coordinated or consolidated pretrial proceedings with the action already pending there. . ." (*Id.* at 3-4).

5. On September 6, 2002, the original Master Consolidated Complaint ("MCC") was filed against 36 Defendants from 22 business operations. Although the MCC specified certain drugs in the text of the allegations, the MCC did not expressly limit itself to a narrow set of drugs manufactured by Defendants for which wrongful AWP manipulation was alleged to exist. As a result, the MCC could fairly be read to raise AWP manipulation regarding ***all*** drugs manufactured by ***all*** Defendants, amounting to thousands of drugs bearing tens of thousands of separate NDC numbers.

6. Motions to dismiss followed, and during this period the Court permitted a narrow range of discovery to move forward.

7. On October 28, 2002, this Court issued an order (after competing filings by the parties) directing Defendants to produce: (i) documents they had previously produced regarding existing or previous state or federal investigations into the use of AWP in pricing of reimbursement of drugs; and (ii) documents they had previously produced in connection with any other legal proceeding in which the Defendant was

alleged to have overstated, misstated a manipulated AWP or otherwise failed to account for certain costs. Plaintiffs were not permitted to move forward with formal discovery beyond the scope of the October order.

8. Following that discovery order, some Defendants produced those documents that they represented were the set of documents that previously had been produced in other legal proceedings. That production, however, was limited to:(i) only those documents that previously had been produced elsewhere; (ii) which related to the scope of the document requests made in those other proceedings; and (iii) which related only to the specific drugs that the other investigative agency was researching (*i.e.*, did not relate to the scope of drugs specifically identified in the MCC).

9. As a result, while the magnitude of documents produced was not insignificant: (i) seven Defendant manufacturers (Amgen, Schering, J&J, Centocor, Bedford, Boehringer and Ortho Biotech) produced no documents at all, and accordingly have provided no discovery in connection with AWP litigation to date; (ii) three Defendant manufacturers (TAP, Pfizer and Novartis) were added to this litigation as part of the AMCC and have produced no discovery in this litigation to date; and (iii) the remaining 17 Defendant manufacturers and groups (Abbott, Astrazeneca, Aventis, Baxter, Bayer, B. Braun, BMS, Dey, Fujisawa, GSK, Hoffman, Immunex, Ortho, Pharmacia, Sicor, Warrick and Watson), have only produced the correspondence or internal memoranda which they previously produced in other AWP investigations involving drugs that were involved in those prior proceedings. With one minor exception, no Defendant has produced actual transaction cost information from the financial records of that Defendant, nor have Defendants provided documents in response to Plaintiffs' previous efforts to obtain information regarding the wide range of kickbacks allegedly engaged in by them[1]. Instead, the information that has been provided relates

[1] There is one small exception to this, a company that produced electronic records for actual transaction costs for a limited number of drugs.

primarily to the injectible drugs investigated by public authorities, and those documents frequently redact information that had not specifically been requested by them.

10. On January 13, 2003, this Court conducted a hearing on the Defendants' initial motions to dismiss. Given statements by the Court during that hearing, Plaintiffs' counsel set out to undertake a comprehensive analysis of all documents that have been produced in order to glean the specific information (factual and financial) available in those documents. In addition, Plaintiffs engaged in a significant effort of informal discovery, including retaining pharmaceutical experts, speaking with pharmaceutical industry insiders, obtaining publicly available reports, purchasing sales information (to the limited extent such information exists) and undertaking a wide range of other activities. This effort was undertaken in anticipation of a ruling by this Court which would direct Plaintiffs' counsel to specify each drug at issue in the case.

11. During this period of time, of course, Plaintiffs did not have access to discovery from Defendants regarding actual transaction pricing and cost information, information that is only available from each of the Defendants.

12. The lack of unavailability of actual transaction cost information, and related financial and factual information concerning off invoice discounts, rebates, gratuities and the like engaged in by Defendants with others in the distribution chain, has also been documented by public reports. At various times in recent years, public investigative agencies have sought to obtain actual transaction cost information from pharmaceutical companies such as Defendants. Those requests were frequently rebuked, and the public reports show that this actual information is only available from Defendants.

13. On May 13, 2003, this Court granted in part, and denied in part, Defendants' motion to dismiss the MCC. *See In Re: Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F. Supp. 2d 172 (D. Mass. 2003) (hereinafter "*AWP Litigation*"). This Court denied the Defendants' motion to dismiss "with respect to any

drug identified in the Complaint together with the allegedly fraudulent AWP published by a named Defendant for that drug." *AWP Litigation*, 45. The Court further stated: "In the event any such amendment is filed, Plaintiff shall clearly and concisely allege with respect to each Defendant: (1) the specific drug or drugs that were purchased from Defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific Plaintiff(s) that purchased the drug." (*Id.*).

14. Following the May ruling, Plaintiffs continued a massive review of each Defendant, its products and its pricing conduct with respect to those products. Plaintiffs continued to use all available public reports, to use all Defendants' documents, to consult with pharmaceutical industry experts and insiders, to acquire sales and the limited price information available for purchase.

15. On June 12, 2003 (about four weeks after the May order), Plaintiffs filed a 301 page, 741 paragraph Amended Master Consolidated Complaint. The AMCC includes six sections of factual allegations.

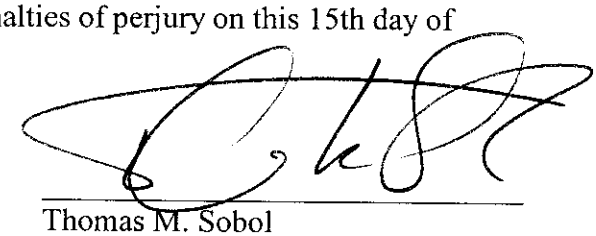
16. Attached hereto as Exhibits A through H are true copies of the following documents:

Exhibit No.	Document Description
A.	Order. *In Re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456 (Apr. 30, 2002)
B.	Order. *In Re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456 (Oct. 28, 2002)
C.	Order. *In Re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456 (May 13, 2003).
D.	Memorandum "Issue considerations on Zofran pricing strategies", Pekarek TO Dawson, Hartsfeld, Pozella and Sluder. (Oct. 25, 1994) (GSK-MDL-Z01-05675)
E.	Price List. Gensia Laboratories, Ltd. and Pharmaceutical Buyers, Inc. (Sicor 00555; 00573; 00614; 00633)
F.	E-Mail and Attachment. Colvin to Ciullo, et al. Re: Redwood Oncology. Attachments include: *Antiemetic Cost Comparison*. (AV-AAA-00116-001125)

G. Chart. *Gamimune N Alternate Site Strategy – Reimbursement.* (BAY005297)

H. Chart. *Market Assessment – US Pricing".* (AABAWP 002746)

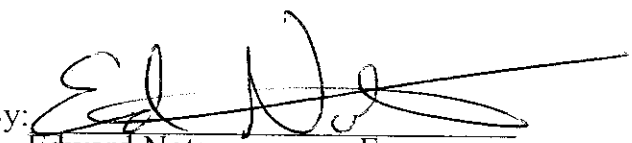
I say the forgoing under the pains and penalties of perjury on this 15th day of September, 2003.



Thomas M. Sobol

CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused true and correct copies of the foregoing AFFIDAVIT OF THOMAS M. SOBOL IN RELATION TO PLAINTIFFS' MOTION TO TAKE ADDITIONAL LIMITED DISCOVERY, to be served on all counsel of record electronically, pursuant to Section D of Case Management Order No. 2., this 15th day of September, 2003.

By: 

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